Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Form PCT/IPEA/416
SK276WO		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP2004/005515	16.04.2004	16.04.2003

International Patent Classification (IPC) or national classification and IPC

Applicant

SEKISUI CHEMICAL CO., LTD.

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 9 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☒ *(sent to the applicant and to the International Bureau)* a total of 4 sheets, as follows:

      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))

      _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- ☒ Box No. I Basis of the report
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2004/005515

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following _____, which is the language of a translation furnished for the purposes of:

- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☐ the international application as originally filed/furnished

☒ the description:

pages 1-33 as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☒ the claims:

nos. 4,6,8,9,16-22,26 as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* 2,3,5,7,10-15,23-25 received by this Authority on 16.02.2005

nos.* _____ received by this Authority on _____

☒ the drawings:

sheets fig. 1 as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☒ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☒ the claims, nos. 1
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing *(specify)*: _____
- ☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing *(specify)*: _____
- ☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	2, 9, 15-22, 26	YES
	Claims	3-8, 10-14, 23-25	NO
Inventive step (IS)	Claims		YES
	Claims	2-26	NO
Industrial applicability (IA)	Claims	2-26	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document 1: JP 9-208788 A (Japan Synthetic Rubber Co., Ltd.), 12 August 1997 & US 5814687 A

Document 2: JP 2003-14764 A (Matsushita Electric Industrial Co., Ltd.), 15 January 2003 & EP 1253427 A & US 2002/177234 A

Document 1 discloses magnetic polymer particles that are configured by incorporating a magnetic material into a polymer, said magnetic polymer particles being characterized in that the number average particle diameter thereof is between 0.02 and 10.00 μm, and in that the polymer is configured from a copolymer that comprises: (A) 50 to 100 parts by weight of a constituent component that includes 20 to 90% by weight of the component (A1) and 80 to 10% by weight of the component (A2); (B) 0 to 50 parts by weight of an ethylenically unsaturated carboxylic acid; and (C) 100 parts by weight of a monomer mixture that includes 0 to 50 parts by weight of a vinyl monomer other than the monomers from the aforementioned components (A) and (B). Therein, document 1 indicates that the powdery supermagnetic material which is configured from an iron oxide has particle diameters of between 80 to 120 Å; that the

magnetic polymer particles are produced from a monomer/magnetic material suspension by means of polymerization; that the component (A2) is a glycidyl (meth) acrylate; that styrenesulfonate is used as the vinyl monomer in component (C); that ethylene glycol dimethacrylate is added as a monomer component; that the content ratio of the supermagnetic material within the magnetic polymer particles is between 21 to 24%; and that it is possible to quantify antigens by bonding the antigens to magnetic polymer particles that have antibodies adsorbed thereto and thereafter magnetically separating the antigens therefrom.

In the invention that is disclosed in document 1 the ethylene glycol dimethacrylate, which is used as a component that constitutes the polymer, is a bifunctional crosslinkable monomer; therefore, the polymer that is disclosed therein can be considered to be a crosslinked polymer. In addition, styrenesulfonate is used as the vinyl monomer that constitutes the polymer; therefore, it is thought that sulfonic acid groups are present on the surface of the polymer in question.

Document 2 discloses the feature of using antibodies that have been labelled with a magnetic substance when taking measurements by means of a biodevice wherein the indicator substance holding section and the determination section have been configured from a porous material.

Claims 3 to 8, 10 to 14 and 23 to 25

The inventions set forth in claims 3 to 8, 10 to 14 and 23 to 25 lack novelty in the light of document 1 cited in the international search report.

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Claim 3 delimits the magnetic material-encapsulating particles by means of the production method therefor; however, the magnetic material-encapsulating particles that are obtained in the end are "magnetic material-encapsulating particles which encapsulate an organic polymer substance and iron oxide particles with an average particle diameter of 1 to 30 nm in a dispersed state within the particles." Therefore, there is no difference between the magnetic polymer particles from the invention that is disclosed in document 1 and the magnetic material-encapsulating particles from the invention that is set forth in claim 3 of the present application in terms of the configurations thereof.

In addition, the magnetic material that is disclosed in document 1 has been subjected to a lipophilization treatment. However, claim 3 does not make any disclosure in relation to a lipophilization treatment; therefore, the question of whether or not the magnetic material has been subjected to a lipophilization treatment has no bearing on the inventions that are set forth in the present application.

Furthermore, it is common practice to produce magnetic particles without modifying the surfaces of the magnetic material in order to impart lipophilic characteristics thereto (if necessary, refer to the documents JP 2000-40608 A and JP 4-3088 B2).

Claims 2, 9 and 15 to 17

The inventions set forth in claims 2, 9 and 15 to 17 do not involve an inventive step in the light of document 1 cited in the international search report.

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

With regards to claim 2, it is common practice to attempt to configure so that the magnetic particles used in immunoassay methods have a uniform magnetic content (if necessary, refer to the document JP 2589618 B2); therefore, a person skilled in the art could configure so that the magnetic material has a uniform content ratio throughout the magnetic polymer particles that are disclosed in document 1, as appropriate. In addition, there is no critical technical significance to delimiting a range of 0.3 or less for the absolute deviation in the content ratio of the magnetic material throughout the magnetic particles in order to establish a reference for determining whether the magnetic material has a uniform content ratio; therefore, a person skilled in the art could delimit a range of 0.3 or less for the absolute deviation in the content ratio of the carbonic element that constitutes the organic polymer substance and the metal element that constitutes the magnetic material, as appropriate.

With regards to claim 9, polyethylene glycol methacrylate is a monomer that is commonly employed during the production of particles that contain a magnetic material; therefore, a person skilled in the art could configure so that polyethylene glycol methacrylate is added as a component of the magnetic polymer particles, as appropriate.

With regards to claims 15, 16 and 17, a person skilled in the art could configure so that the linkers for introducing an epoxy group that is capable of bonding with an antigen or an antibody are bonded to the magnetic polymer particles, and could further select a polyethylene glycol diglycidyl ether for use as the

linker in question, as appropriate.

Claims 18 to 22

The inventions set forth in claims 18 to 22 do not involve an inventive step in the light of document 1 cited in the international search report.

With regards to claim 18, an organic peroxide compound is added to the monomer/magnetic material suspension as a polymerization initiator in the invention that is disclosed in document 1. However, the technical feature of obtaining a magnetic material by processing iron ions by means of an oxidizing agent is well known; therefore, it would have been easy for a person skilled in the art to conceive of substituting iron ions for the magnetic material that is added to the suspension in the invention that is disclosed in document 1 and then configuring so that the magnetic material is generated during the polymerization process that is initiated via the action of the polymerization initiator.

In addition, the magnetic material that is disclosed in document 1 has been subjected to a lipophilization treatment. However, claim 18 does not make any disclosure in relation to a lipophilization treatment; therefore, the question of whether or not the magnetic material has been subjected to a lipophilization treatment has no bearing on the inventions that are set forth in the present application.

Furthermore, it is common practice to produce magnetic particles without modifying the surfaces of the magnetic material in order to impart lipophilic characteristics thereto (if necessary, refer to the documents JP 2000-40608 A and JP 4-3088 B2).

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Claim 26

The invention set forth in claim 26 does not involve an inventive step in the light of document 1 and document 2 cited in the international search report.

It would be easy for a person skilled in the art to conceive of substituting the magnetic polymer particles that are disclosed in document 1 for the magnetic substance that is disclosed in document 2.

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International application No.
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Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
JP 2004-163421 A	10.06.2004	21.10.2003	21.10.2002

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)